GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA

UNSTARRED QUESTION NO:1185
ANSWERED ON:02.05.2016
Rejection of Made-in-India Products by USFDA
Khuba Shri Bhagwanth

Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether the US Food and Drug Administration (USFDA) has rejected a large number of Made-in-India products during the last five years;
(b) if so, the details thereof;
(c) whether the production of these products was below standard quality; and
(d) if so, the details thereof along with the action taken by the Government in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (INDEPENDENT CHARGE)
(SMT. NIRMALA SITHARAMAN)

(a) & (b) According to Import Refusal Report data available on the US FDA website (http://www.accessdata.fda.goviscripts/importrefusals/), 12,012 refusals of Indian products were recorded from January, 2011 to March, 2016.

(c) & (d) The reasons given for the refusals include misbranding, adulteration, packaging, labelling, pesticides, unapproved products, etc. Among the steps taken by the Government include tightening labelling rules and making it mandatory for companies to clearly mention the dates of manufacturing, best before use and expiry dates, improving pre-export inspection, greater emphasis on standards through sensitization of exporters for compliance of regulatory issues through export promotion agencies and also taking up the issues at bilateral trade forums, wherever appropriate.

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